



26 March 2026
EMA/56282/2026
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion¹ (initial authorisation)

Zepzelca

lurbinectedin

On 26 March 2026, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Zepzelca², intended for the treatment of extensive-stage small cell lung cancer (ES-SCLC).

The applicant for this medicinal product is Pharma Mar S.A.

Zepzelca will be available as a 2 mg and 4 mg powder for concentrate for solution for infusion. The active substance of Zepzelca is lurbinectedin, an antineoplastic agent (ATC code: L01XX69). Lurbinectedin inhibits the oncogenic transcription process by binding to CG-rich DNA sequences, evicting transcription factors from their binding sites and stalling elongating RNA polymerase II and its specific degradation by the ubiquitin/proteasome machinery, which leads to cell cycle arrest and tumour cell apoptosis.

The benefits of Zepzelca as maintenance treatment in combination with atezolizumab in patients with ES-SCLC whose disease had not progressed after induction therapy are improved progression-free survival (PFS) and overall survival (OS), compared with maintenance treatment with atezolizumab alone. The most common side effects of Zepzelca are nausea, fatigue, anaemia, thrombocytopenia, and neutropenia.

The full indication is:

ZEPZELCA, in combination with atezolizumab, is indicated for the maintenance treatment of adult patients with extensive-stage small cell lung cancer (ES-SCLC) whose disease has not progressed after first-line induction therapy with atezolizumab, carboplatin and etoposide.

Zepzelca therapy should be initiated and supervised by health professionals experienced in the use of anticancer products.

Detailed recommendations for the use of this product will be described in the summary of product characteristics (SmPC), which will be published on the EMA website in all official European Union languages after the marketing authorisation has been granted by the European Commission.

¹ Summaries of positive opinion are published without prejudice to the Commission decision, which will normally be issued 67 days from adoption of the opinion

² This product was designated as an orphan medicine during its development. EMA has reviewed the information available to date and determined that the orphan designation should be maintained

